

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY****REGION 8****999 18TH STREET- SUITE 300****DENVER, CO 80202-2466****Phone 800-227-8917****<http://www.epa.gov/Region08>****ADMINISTRATIVE
RECORD****DATE: September 29, 2005****SUBJECT: Amphibole Mineral Fiber Contamination of Various Source Materials in Residential and Commercial Areas of Libby Pose an Imminent and Substantial Endangerment to Public Health****FROM: Aubrey Miller MD, MPH**
Senior Medical Officer / Science Support Coordinator
Libby Asbestos Site**TO: Jim Christiansen, Remedial Project Manager**
Libby Asbestos Site**I. PURPOSE**

This memorandum presents the rationale for determination of imminent and substantial endangerment to public health from asbestos contamination in various types of source materials at residential and commercial properties in and around the community of Libby, Montana. This memorandum confirms and extends similar issues and conclusions discussed in previous Endangerment Memorandums prepared by Dr. Chris Weis, former Science Support Coordinator, for the Libby Site (Weis, 2000; Weis, 2001a, Weis, 2001b); EPA Region 8 Action Memorandums prepared by Region 8 On-scene Coordinator Paul Peronard and Acting Regional Administrator Jack McGraw (EPA R8 Action Memorandums 2000; 2001; 2002); and EPA Responses to Comments from WR Grace on the Administrative Record (EPA R8 Responses to WRG Comments 2001 & 2002).

II. SUMMARY OF FINDINGS

- 1) Asbestos fibers of the type that occur in vermiculite ore from the mine in Libby are hazardous to humans when inhaled.
- 2) Asbestos mineral fibers that are characteristic of those that occur in materials from the Libby mine are present in a variety of different source materials at residential and commercial locations in and around the community of Libby. Outdoor source materials include yard soil, garden soil, driveway material, and assorted mine waste

materials, while indoor source materials include house dust and vermiculite insulation.

- 3) Disturbance of asbestos-contaminated source materials by activities similar to those that are likely to be performed by area residents and workers can result in elevated concentrations of respirable asbestos fibers in air.
- 4) The concentrations of fibers in air generated by disturbance of source materials may exceed OSHA occupational standards (OSHA 1994) and EPA cancer risk guidelines (EPA 1986). Further such guidelines may underestimate the actual risk for adverse health outcomes associated with airborne exposure to Libby Amphibole (LA).

On this basis, it is concluded that: a) contaminated source materials at this site, such as soil and soil-like media, dust, and vermiculite insulation, contain elevated concentrations of asbestos minerals and can serve as a source of on-going release of hazardous fibers to air, b) disturbance of Libby Amphibole (LA) contaminated source materials will result in a complete pathway for human exposure, and c) it is necessary to reduce or eliminate pathways of exposure for residents, workers, and others who may disturb these contaminated source materials.

III. BACKGROUND

Vermiculite was discovered in the Rainy Creek Mining District of Lincoln County, Montana, in 1916 by E.N. Alley. Alley formed the Zonolite Company and began commercial production of vermiculite in 1921. Another company, the Vermiculite and Asbestos Company (later known as the Universal Insulation Company), operated on the same deposits (BOM, 1953). W.R. Grace purchased the mining operations in 1963 and greatly increased production of vermiculite until 1990 when mining and milling of vermiculite ceased.

Vermiculite ore bodies on Zonolite Mountain contain amphibole asbestos at concentrations ranging up to nearly 100% in selected areas (Grace). Although early exploration and mining efforts by the Zonolite Company focused upon the commercial viability of fibrous amphibole deposits found on Zonolite Mountain (DOI, 1928), no commercial production of asbestos from the Libby mine is reported. During early mining operations, airborne fiber concentrations at the mine exceeded 100 fibers/cc in several job classifications (Amandus et al, 1987a). Historical airborne fiber concentrations in the residential area of Libby exceeded the present occupational Permissible Exposure Level (PEL) of 0.1 fiber/cc established by OSHA in 1994 (MRI, 1982; Eschenbach deposition). This exposure limit is recognized as being associated with significant risk (3.4 additional asbestos-related cancers per 1000 individuals as per OSHA estimates) but is the practical lower limit of detection using phase contrast microscopy (PCM) as a measurement technique (OSHA, 1994).

Residual fiber contamination from the subject facilities continues to present potential exposure to

workers, residents, and visitors at these facilities, but is presently being addressed under removal authorities provided in the Comprehensive Environmental Response Compensation and Liability Act Section 104 (CERCLA or Superfund). These actions by the U.S. Environmental Protection Agency Region 8 office in Denver, CO began on November 22, 1999 and continue today. The investigative team is working closely with Local, State, and other Federal Agencies to determine the nature and extent of mineral fiber contamination throughout Libby, and to take appropriate action to protect the health of current residents and workers.

IV. ENDANGERMENT RATIONALE

Threats to public health have been clearly demonstrated at the Libby site with regard to: 1) disease from airborne exposure to Libby Amphibole fibers, and 2) exposures resulting from disturbance of contaminated source materials.

A. Disease from Exposure to Libby Amphibole Fibers

Exposure to airborne asbestos fibers resulting from disturbance of ore products or wastes from the Zonolite Mountain in Libby, Montana is hazardous to human health.

The risk of developing an asbestos-related disease depends on fiber characteristics, the level and duration of exposure, time since first exposure, the individual's smoking history, and the individual's response to the presence of asbestos fibers in pulmonary tissue. In general the longer a person is exposed to asbestos and the greater the intensity of the exposure, the greater the likelihood for asbestos-related health problems. While some forms of disease, especially cancers, may take as long as forty years to develop, there is concern that even short-term exposures may have significant adverse health impacts. This is particularly true for children, in whose lungs the presence of fibers may be able to exert their toxic effects for many more years as compared to exposures during adulthood.

1. Libby Site Exposures and Disease

The health effects from airborne exposure to the more common commercially used and regulated asbestos mineral forms (chrysotile, tremolite, actinolite, anthophyllite, amosite, crocidolite) include: (1) pleural disease (plaques, diffuse thickening, calcifications, and pleural effusions), (2) interstitial disease (asbestosis), (3) lung cancer, and (4) mesothelioma (a rare cancer of mesothelial cells in the pleura or peritoneum). The observed health effects associated with exposure to asbestiform amphibole fibers (Libby Amphibole) (Meeker, 2003) at the Libby site have been well documented and are clearly consistent, and perhaps even more severe, than those illnesses seen with the more common asbestos mineral exposures (as noted below).

Studies performed in the early 1980's by researchers from McGill University (McDonald 1986a-b) and the Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) (Amandus 1987a-c) found that former employees of the Libby vermiculite mine had significantly increased pulmonary morbidity and mortality from asbestosis and lung malignancies. Researchers at NIOSH who studied the annual

chest x-rays of mine and mill workers with at least 5 years tenure (between 1975 and 1982) also found an increased prevalence of the radiographic abnormalities associated with asbestos-related disease. A recent follow-up study of Libby vermiculite workers that were previously evaluated in the 1980's, found that "this small cohort of vermiculite miners, exposed to amphibole fibers in the tremolite series, has suffered severely from both malignant and non-malignant respiratory disease"(McDonald, 2002). The overall proportionate mortality among the group for mesothelioma (4.2%) was extremely high, being similar to that seen for crocidolite (considered by many to be the most toxic form of asbestos) miners in South Africa (4.7%) and Australia (3.9%) (McDonald 2002; McDonald 2004). For comparison, the age-adjusted incidence of mesothelioma in the United States (1992-2002) was about 0.001% (1 case per 100,000) with the occurrence of cases being extremely rare prior to age 50 (SEER, 2005).

More recent studies completed at the Libby site have also found increased mortality and morbidity among former workers, as well as, others in the community without any direct occupational exposures to the mine or processing activities. A mortality study conducted by investigators from the CDC, Agency for Toxic Substances and Disease Registry (ATSDR) found markedly elevated death rates of asbestosis, lung cancer, and mesothelioma for the Libby Community for the 20-year period examined (1979–1998). Mortality from asbestosis was approximately 40 times higher than the rest of Montana and 60 times higher than the rest of the United States (ATSDR 2000, ATSDR 2002a).

Large-scale medical screening of over 7300 individuals that worked or lived in Libby for at least six months prior to 1990, found significantly increased rates of asbestos-related radiologic abnormalities. Approximately 18% (1186/6668) of the participants with asbestos-related pleural abnormalities were identified by at least 2 out of 3 B-readers. The prevalence of pleural abnormalities increased with increasing exposure pathways, ranging from 6.7% for those who were not able to identify any specific exposure pathways aside from living in Libby to 34.6% for those who reported 12 or more specific exposure pathways. The majority of individuals (>70%) with pleural abnormalities did not directly work for the mine or processing operations, or with any secondary contractors for the mine (Peipins 2003, EHP 2004). Findings of asbestos-related pleural disease were also documented in a case-series involving a small group of Libby residents with no history of any occupationally-related asbestos exposures (ATSDR 2002b). In another recent study, computed tomography (CT) scans were evaluated as a screening tool for detecting asbestos-related lung abnormalities in persons who had indeterminate chest x-rays (only 1 of the 3 B-readers reported pleural abnormalities on the participant's chest x-ray) during the medical screening in Libby, Montana. These were individuals that were not counted by investigators as having "asbestos-related abnormalities" for the analysis or reporting of data from the medical screening. Of the 353 participants with indeterminate chest x-rays (55 former vermiculite mine and mill workers, 99 household contacts, 199 persons with exposure to vermiculite due to past direct recreational behaviors), CT scans detected pleural abnormalities in 98 persons or 28% of all those tested (ATSDR 2003), indicating that the actual prevalence of asbestos-related pleural disease reported in the community by Peipins et. al.(Peipins 2003), is likely to be conservative.

A recent expert review of the medical literature by the American Thoracic Society (ATS) that

focused on “non-malignant asbestos disease” reported the following findings with regard to asbestos-related pleural disease: 1) slow progression of asbestos-related pleural disease is typical, with up to 85% of heavily exposed workers and 17% of environmentally exposed populations showing progression of their disease over time, 2) the presence of asbestos-related pleural disease has been associated with a greater risk of mesothelioma and lung cancer compared with subjects of comparable histories of asbestos exposures who do not have such abnormalities, and 3) epidemiologic studies have shown a significant reduction in lung function attributable to both circumscribed and diffuse pleural fibrosis, even in the absence of radiological evidence of interstitial fibrosis (asbestosis) (ATS 2004). Such findings of disease progression and loss of pulmonary function has also been recently documented for individuals with exposure to Libby Amphibole. This study evaluated 123 patients (86 former workers, 27 family members of former workers, 10 non-occupational exposures) with exposure to Libby Amphibole for changes in pulmonary function over time. Marked progressive loss of pulmonary function was found in 94 (76%) of these patients, with the majority having predominantly only pleural disease (Whitehouse 2004).

2. Offsite Exposures and Disease

In addition to the Libby site, offsite occupational exposures to Libby Amphibole associated with processed vermiculite ore and vermiculite products (having much lower levels of contamination) have also documented the extremely hazardous nature of this material. A study of 513 workers at a manufacturing plant in Marysville, Ohio that handled processed vermiculite ore found an increased prevalence of shortness of breath, pleuritic chest pain, and radiographic pleural abnormalities in association with cumulative asbestos exposures as low as 1-10 fibers/ml-year (Lockey, 1984). Preliminary results from a recent follow-up evaluation of 236 of the original Ohio workers found that the overall prevalence of pleural plaques had increased from 4% among the overall cohort in 1980 to 26.3%. The increase in pleural changes was found in both low and higher exposure categories and this increase was significantly associated with cumulative exposure ($p < 0.05$). Percent of workers with pleural changes increased in relation to cumulative exposure quartiles: 1st quartile 5.1% (0.0007-0.361 fiber/cc-year), 2nd quartile 22.0% (0.362-1.042 f/cc-yr), 3rd quartile 33.9% (1.043-2.564 f/cc-yr), and 4th quartile 44.1% (2.565-28.11 f/cc-yr). The manufacturing facility had ceased using Libby vermiculite ore in 1980 and subsequently used vermiculite ore from other sources that reportedly contained no asbestos or asbestiform minerals (Rohs, 2005). Progressive disease from exposure to Libby Amphibole fibers was also noted in a case study that reported the occurrence of fatal asbestosis in an individual 50 years after working at an offsite vermiculite processing plant for a few months at about age 17 (Wright, 2002). In addition to occupational exposures, cases of fatal non-occupational asbestos disease associated with exposures to contaminated vermiculite have been reported. In one case, exposures that stemmed from playing for a few years as a child in contaminated vermiculite waste materials around a former Libby vermiculite processing facility was associated with the development of asbestosis and fatal lung cancer (Srebro, 1994). In another case, exposure to vermiculite attic insulation was associated with the development of fatal mesothelioma in a homeowner (Harashe v. Flintkote, 1993).

B. Asbestos Exposures Resulting From Contaminated Bulk Materials

Disturbance of soils, dusts, insulation, garden products, and other bulk materials contaminated with asbestiform minerals from Libby, Montana may result in a complete pathway for airborne human exposure. Depending on various environmental factors (e.g., room ventilation, wind, humidity) and the nature of the activities, airborne exposures may exceed available OSHA standards (OSHA 1994) and EPA health guidance (EPA 1986).

1. Soils & Dust

Asbestos fibers in soil or dust are not inherently hazardous to humans if left undisturbed. However, most soils and dusts are subject to disturbance, either now or in the future, by many different types of activities that are common for residents or workers. The presence of LA contaminated exterior soils and interior dusts poses an exposure hazard for individuals who may frequent and disturb such materials on a routine basis. Asbestos contaminated source materials, such as surface soils, may also serve as an ongoing reservoir for fiber emission and contamination into co-located indoor environments or vehicles, through air currents or transport via human activity (i.e., soil adherence to shoes). Once contaminated, such areas or vehicles can then in-turn serve as secondary sources of ongoing human exposure.

Ongoing EPA investigations at the Libby site have demonstrated that mechanical disturbance of asbestos-contaminated soil or dust by activities similar to those that are likely to be performed by area residents or workers results in elevated levels of respirable asbestos fibers in air. EPA Region 8 evaluated several scenarios involving disturbance of contaminated soils and dusts such as vehicular traffic on Rainy Creek Road, active cleaning of households, sweeping of dust, and rototilling of soil. These scenarios clearly demonstrated that asbestos fibers may be released from soils and dust into the personal breathing zones by a variety of common activities and that a complete pathway exists by which asbestos-contaminated source materials may cause inhalation exposure of area residents and workers. Additionally, EPA found that the concentrations of fibers in air generated by disturbance of source materials may exceed OSHA standards for acceptable occupational exposure, as well as, exceeding EPA's typical excess cancer risk range (1E-04 to 1E-06) by an order of magnitude or more. (Weis, 2001a; Weis, 2001b).

In addition to the Libby site, investigations by Region 8 researchers found that surface soils containing concentrations <1 % of LA by polarized light microscopy (PLM) when disturbed by raking and mechanical blowing scenarios, resulted in airborne asbestos exposures easily approaching, and in one sample exceeding the OSHA PEL (Miller, 2004). These findings are consistent with the results of EPA investigations at other sites, as well as, evaluations performed by other government agencies and researchers. For example, disturbance scenarios simulating baseball, basketball, soccer, bike riding, running, playing on a children's playground, and gardening in low concentration asbestos contaminated soils (<1%) in El Dorado Hills, California, found complete exposure pathways and significantly elevated airborne exposures (EPA Region 9, 2005). Published research performed by Addison et. al. (Addison, 1988) showed that soils containing asbestos concentrations ranging from 1.0 to 0.001% can generate elevated airborne concentrations when disturbed under controlled conditions. Currently EPA has not established an asbestos level in soil or dust below which an exposure does not pose a risk, under any of its

regulatory programs. The 1% asbestos concentration levels commonly cited and used for regulatory purposes under the EPA Toxic Substances Control Act (TSCA) abatement program, was established on the basis of analytical capability at the time and does not have any relationship to the actual health risks associated with the handling or disturbance of the contaminated material in question (EPA, 2004). Based on increased recognition of this issue and advancement of the science, California EPA is currently in the process of adopting new guidance for asbestos contaminated soils at schools which suggests that soils containing asbestos concentrations less than 1% asbestos by weight may need to be remediated, especially in high use areas such as playing fields and dirt roads (Cal/EPA, 2004).

2. Libby Vermiculite Products

Disturbance of vermiculite products (e.g., vermiculite insulation, vermiculite garden products) originating from the Libby mine can result in elevated levels of respirable asbestos fibers in the air. Activities similar to those likely to be performed by homeowners and workers that disturb vermiculite products containing even trace amounts or non-detectable concentrations of asbestos by PLM methods, have been demonstrated to release airborne concentrations of fibers which can exceed OSHA and EPA guidelines (Weis 2001b; Versar, 2002; EPA Region 10, 2000, Pinchin 1997, Barbanti v. WR Grace Case No. 00201756-6). Recognition of this finding has resulted in national warnings by EPA, ATSDR, and NIOSH concerning the dangerous nature of vermiculite insulation used in residences and businesses throughout the United States (EPA & ATSDR, 2003; NIOSH Fact Sheet 2003).

V. CONCLUSIONS

The rationale for determination of imminent and substantial endangerment from asbestos-contaminated source materials in residential areas of Libby is four-fold:

- 1) Asbestos fibers from the Libby mine site are hazardous to humans as evidenced by the occurrence of asbestos-related disease in area residents and workers. Workers and area residents exposed to asbestos fibers from the Libby mine site have been found to have increased mortality and morbidity from asbestos-related conditions, including asbestosis, pleural fibrosis, lung cancer, and mesothelioma. Asbestos-related lung diseases have also been observed in area residents with no direct occupational exposures, including family members of mine workers, and even in those with no known association with the vermiculite mining or processing activities;
- 2) Asbestos fibers can be detected in several types of source materials (yard soil, garden soil, driveway material, waste piles, indoor dust, vermiculite insulation) at multiple locations in and around the residential and commercial areas of Libby. These contaminated materials constitute a potential source of asbestos exposure to workers and area residents;
- 3) Asbestos fibers in contaminated source materials may be released into air by a variety

of activities similar to those that area residents or workers may engage in under normal living conditions. This demonstrates that a complete exposure pathway exists by which asbestos-contaminated source materials may result in airborne exposures of area residents or workers;

- 4) The concentrations of asbestos fibers that occur in air following mechanical disturbance of source materials may reach levels of potential human health concern, as evidenced by airborne concentrations which can exceed OSHA occupational standards and EPA cancer risk guidelines. Furthermore, given the mineralogic and morphologic characteristics of Libby Amphibole fiber it is likely that the EPA cancer risk guidance may underestimate actual cancer risks for this population.

Asbestos contamination exists in a number of potential source materials at multiple locations in and around the residential and commercial areas of Libby. These potential source materials include area soils (yards, gardens, playgrounds, etc.), driveway material, waste piles, indoor dust, and vermiculite insulation. If these contaminated sources are disturbed by human activities, fibers are likely to be released to air. Chronic, and even higher dose short-term, exposures to airborne LA fibers pose an increased risk for asbestos-related lung diseases. Sampling events involving contaminated source materials at the Libby site, and even at offsite vermiculite processing facilities, consistently indicate the presence of amphibole asbestos which can result in airborne exposures of concern. The concentration levels released to air depend on the concentration of fibers in the source material and on the nature of the disturbance. Risks are proportional to the concentration of fibers in air and the frequency and duration of exposure. While data are not yet sufficient to perform reliable human-health risk evaluations for all sources and all types of disturbance, it is apparent that releases of fiber concentrations higher than OSHA standards may occur in some cases (mainly those associated with active disturbance of vermiculite), and that screening-level estimates of lifetime excess cancer risk can exceed the risk range of $1E-04$ usually used by EPA for residents and workers that are unaware of the exposure. In addition to the excess cancer risks, the extremely high prevalence of asbestos-related pleural disease among Libby residents is of great public health concern and is not addressed by the currently available EPA risk guidelines. The occurrence of such high levels of non-occupational asbestos-related disease among Libby residents is extremely unusual, suggesting that a combination of factors likely related to elevated levels and duration of environmental exposures through multiple exposure pathways, and perhaps an increased inherent toxicity of this form of amphibole asbestos, may be involved. On this basis, I recommend that steps be taken to further identify, quantify, minimize and/or eliminate pathways of human exposure to amphibole asbestos in the residential and commercial areas of Libby.

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